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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,723	03/01/2002	Martin Caldwell	1890-0019	1585

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Nixon Peabody
Suite 800
8180 Greensboro Drive
McLean, VA 22102

EXAMINER	
ROBERTS, PAUL A	

ART UNIT	PAPER NUMBER
3731	12

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,723	CALDWELL ET AL.	
	Examiner	Art Unit	
	Paul A Roberts	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9* is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 May 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,984,564 to Yuen.

Regarding claim 1, Yuen discloses a device for use in minimally invasive surgery using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (col. 1, ll. 14-24). The device has a distal body cavity engagement means for insertion into the incision to locate the device in position, a proximal fixing means for attaching the device to a patient's skin (Fig. 2: element 12), and a sleeve connected between the body cavity engagement means and the fixing means defining an access port (Fig. 2: element 16). The device includes a sealing means (Fig. 2: element 16), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position (col. 4, ll. 34-52). The inflatable cuff, 16, is made up of pockets that are inflatable and provide an opening within the device. In Fig. 3, the sealing means is provided by an inflatable first seal for engaging and retracting the incision (element 34: "outer wall") and a second inflatable seal (element 32: "inner wall") for sealing the lumen of the tube or sleeve bore (col. 4, ll. 28-36).

Regarding claim 3, Yuen discloses in Fig. 2 a device in which the body cavity engagement means (14) is provided by a distal ring formed for insertion into the incision.

Regarding claim 4, Yuen discloses in Fig. 2 a device in which the fixing means (12) is provided by a proximal ring for engaging with a patient's skin.

Regarding claim 6, Yuen discloses in Fig. 3 a device in which the first seal (34) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 3, ll. 28-36). As the cuff is inflated, the outer wall (first seal) of the cuff becomes inflated, expands, and forms a seal with the incision (col. 4, ll. 40-44).

Regarding claim 7, Yuen discloses in Fig. 3 a device in which the second seal (32) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation that is capable of preventing excessive loss of gas through the access port (col. 3, ll. 28-36). When the cuff is inflated, the inner wall (second seal) expands and is capable of being inflated to prevent loss of gas through the access port (col. 4, ll. 40-44).

Regarding claim 8, Yuen discloses in Fig. 2 a device in which the second seal (32) is operatively connected and mounted within the first seal (34).

2. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,545,179 to Williamson, IV.

Regarding claim 1, Williamson, IV discloses a device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (Abstract). The device has a distal body cavity engagement means (Fig. 5: element 40) for insertion into the incision to locate the device in position, a proximal fixing means for attaching the device to a patient's skin (Fig.

5: element 27), and a sleeve connected between the body cavity engagement means and the fixing means defining an access port (Fig. 5: element 26). The device includes a sealing means (Fig. 5: elements 35 and 34), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. The sealing means is provided by an inflatable first seal (35) for engaging and retracting the incision and a second inflatable seal (34) for sealing the lumen of the tube or sleeve bore.

Regarding claim 3, Williamson, IV discloses in Fig. 5 a device in which the body cavity engagement means (40) is provided by a distal ring formed for insertion into the incision. The distal end, 35 and 37 of 34, forms a ring shape and is used for insertion. In Fig. 1, the engagement means (element 23 in this Figure) is shown inserted into the incision.

Regarding claim 4, Williamson, IV discloses in Fig. 5 a device in which the fixing means is provided by a proximal ring (27) for engaging with a patient's skin.

Regarding claim 5, Williamson, IV discloses in Fig. 5 a device in which the proximal ring (27) has an associated connector ring (25) for receiving additional seals or medical instruments.

Regarding claim 6, Williamson, IV discloses in Fig. 5 a device in which the first seal (35) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 5, ll. 58-67; col. 6, ll. 1-3). The outer inflatable sleeve, 35, comprises of element 40, which is inflated and seals the incision.

Regarding claim 7, Williamson, IV discloses in Fig. 5 a device in which the second seal (34) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation

that is capable of preventing excessive loss of gas through the access port (col. 2, ll. 60-64; col. 5, ll. 63-67). The second seal is the inflation of the "inner channel" or "inner wall of the central channel" that compresses and provides a seal.

Regarding claim 8, Williamson, IV discloses in Fig. 5 a device in which the second seal (34) is operatively connected and mounted within the first seal (35).

3. Claims 1, 3, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,634,937 to Mollenauer et al.

Regarding claim 1, Mollenauer et al. disclose a device for use in minimally invasive surgery using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (Abstract). In Fig. 17, the device has a distal body cavity engagement means (61) for insertion into the incision to locate the device in position, a proximal fixing means (60) for attaching the device to a patient's skin, and a sleeve connected between the body cavity engagement means and the fixing means defining an access port. In Fig. 12, the device includes a sealing means (49, 50), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. The sealing means is provided by an inflatable first seal (50) for engaging and retracting the incision and a second inflatable seal (49) for sealing the lumen of the tube or sleeve bore (col. 10, ll. 35-38, ll. 54-65).

Regarding claim 3, Mollenauer et al. disclose in Fig. 17 a device in which the body cavity engagement means is provided by a distal ring (61) formed for insertion into the incision. In Fig. 12, the distal end of the balloon is formed by the outer balloon membrane, 50, and the inner

balloon membrane, 49, which both create a ring shape that is inserted into the incision (col. 10, ll. 26-30).

Regarding claim 4, Mollenauer et al. disclose in Fig. 17 a device in which the fixing means (60) is provided by a proximal ring for engaging with a patient's skin. In Fig. 12, the proximal end of the balloon is formed by the outer balloon membrane, 50, and the inner balloon membrane, 49, which both create a ring shape that remains on the skin (col. 10, ll. 30-33).

Regarding claim 6, Mollenauer et al. disclose a device in which the first seal (Fig.12: element 50) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 10, ll. 10-15, 55-60). In Fig. 17 as the balloon is inflated, the first seal expands against the skin and subcutaneous fat (elements 27 and 33)

Regarding claim 7, Mollenauer et al disclose a device in which the second seal (Fig.12: element 49) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation to prevent excessive loss of gas through the access port (col. 10, ll. 60-64) .

Regarding claim 8, Mollenauer et al disclose in Fig. 12 a device in which the second seal (49) is operatively connected and mounted within the first seal (50).

Response to Arguments

Applicant's arguments filed 11/7/03 have been fully considered but they are not persuasive.

4. Argument 1, page 5, "Yoon does not prevent substantial leakage of gas from the body of the cavity". If a surgical instrument is placed into the retractor as intended by Yuen, the device will substantially prevent leakage of gas from the body cavity. The device is constructed from a

flexible plastic material. A device with this shape made out of flexible plastic would inherently conform to the shape of a large object placed within its center bore.

5. Argument 2, page 6, the Mollenauer device discloses a proximal fixing means 60, the distal engagement means 61, and the sleeve 52. The device as claimed doesn't require the parts not to compose a larger element such as the balloon. The same is true for the Williamson IV reference.

6. Argument 3, page 6, the scope of what is and isn't a seal is very important to this argument. A seal can be a physical object such a rubber gasket. A seal can also be the result of placing to object in close proximity. For example, placing one's hands together firmly creates a seal between said hands. Using Mollenauer as an example, when the device 34 is inserted, a first seal is formed along member 49 from the proximal end to the distal end of the device. A seal separate and distinct from the first seal is formed between 52 and 32. Thus two seals are formed.

Allowable Subject Matter

Claim 9 is allowed. The following is a statement of reasons for the indication of allowable subject matter: the device of claim 1 with a perforated wall defining a substantially cylindrical tube was not found in the search.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Roberts
Paul.Roberts@uspto.gov
04/07/04

4/16/04
MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700